

### **Remarks**

Claims 22-25 are pending in the application. In the Final Office Action mailed June 3, 2003, the Examiner rejected claims 22-25 under 35 U.S.C. 103(a) as being unpatentable and under the judicially created doctrine of obviousness-type double patenting.

#### Examiner's comments regarding Schumm et al.

In the Office Action, the Examiner stated that "With respect to the inquiry posed to applicant on March 28, 2003 with respect to a meeting abstract or additional documents from the Fourth International Symposium on Human Identification, the examiner has not received a response. Therefore, the 102(a) has been withdrawn in view of the declaration, however, the examiner has not been able to make a final determination with respect to a 102(b) type inquiry."

The undersigned was informed by Promega Corporation that on or about February 27, 2003, Examiner Goldberg contacted, or caused Mona Smith, a USPTO employee, to contact Ms. Cynthia J. Sprecher, an inventor on the instant application, to inquire about an article entitled "Development of Nonisotopic Multiplex Amplification Sets for Analysis of Polymorphic STR Loci" by Schumm *et al.* (Proceedings from the Fourth International Symposium on Human Identification, pages 177-187), which Applicants had submitted to the U.S.P.T.O. in an information disclosure statement and which was cited as 102(a) art against the claims in the previous Office Action. The Schumm et al. publication was made available to the public less than one year prior to the filing of the application to which the instant application claims priority and is a manuscript of a presentation given by Dr. James W. Schumm at the Symposium, which was held from September 26, 1993 through September 29, 1993. The undersigned was advised that following the Examiner's inquiry, Ms. Rosemarie Kirwin, who was employed by Promega Corporation, subsequently faxed a copy of the article to Ms. Mona Smith or Examiner Goldberg.

On March 28, 2003, the Examiner contacted the undersigned to inquire as to whether the Dr. Schumm had distributed an abstract of the presentation at the Symposium. The undersigned requested that the Examiner make the inquiry on the record, and that any future inquiry concerning prosecution of this application be directed to the attorneys of record rather than to Applicants.

Applicants have advised the undersigned that Promega Corporation has no record of having distributed an abstract at the aforementioned Symposium.

#### Comments regarding the finality of the Office Action

The Examiner asserted that new grounds for rejection were necessitated by Applicants' amendment, and that the finality of the rejection was, therefore, proper. However, Applicants

merely rewrote claims 22-25 as independent claims and did not introduce any further limitations.

In view of the arguments below, Applicants request reconsideration and allowance of the claims.

#### Rejections under 35 U.S.C. 103(a)

##### Caskey and Kimpton (Int. J. Leg. Med.) in view of Kimpton or Fregeau or Urquhart

The Examiner has rejected claims 22-25 under 35 U.S.C. 103(a) as being unpatentable over Caskey (U.S. Patent No. 5,364,759) and Kimpton (Int. J. Leg. Med. 106:302-311, 1994) in view of Kimpton (PCR Methods and Applications, 1993) or Fregeau (BioTechniques, 1993) or Urquhart (Int. J. Leg. Med. 107:13-20, 1994).

Applicants reassert the arguments made in response to the previous Office Action. The Examiner has acknowledged that none of the five cited references teaches or suggests the particular combinations of loci claimed. Never-the-less, the Examiner concluded that, although the art does not combine to teach the particular combinations of loci recited in the claims, it would have been prima facie obvious to modify the teachings of Caskey and Kimpton with the loci of Fregeau, Kimpton, or Urquhart to obtain the claimed invention based on the teachings of Caskey and Kimpton, because Fregeau, Kimpton, or Urquhart provide motivation to choose any reasonable number of loci in desired combinations, and implement multiplex amplification thereof by routine optimization of PCR methodology.

Applicants respectfully submit the combination of references does not teach or suggest the method of any of claims 22-25. As the Examiner acknowledged, the references do not combine to teach the specific combination of loci recited in the claimed invention. In fact, the references indicate that the selection of STR loci that can be co-amplified is not a trivial matter, but rather, one that would require a considerable amount of experimentation.

##### Caskey in view of GenBank STR loci

Claims 22-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Caskey in view of GenBank STR loci HUMTH01, HUMTPOX, HUMF13A01, HUMFABP, HUMMYPOK, HUMBFXIII, HUMHPRTB, HSAC04, HUMCYP19, and HUMPLA2A1. Caskey is cited for the reasons summarized above. Caskey is quoted asserting knowledge of the sequence of an STR and its flanking sequences permit primer design and synthesis. Caskey is further said to describe the empirical nature of multiplex amplification reactions and optimization. STR loci HUMTH01, HUMTPOX, HUMF13A01, HUMFABP, HUMMYPOK, HUMBFXIII, HUMHPRTB, HSAC04, HUMCYP19, and HUMPLA2A1 are disclosed in GenBank.

As noted previously, in Applicants' prior response, Caskey discloses only two multiplexes (duplexes), one of which produced overlapping alleles. Caskey provides no teaching as to which loci could be amplified to produce results that could be evaluated in any meaningful way. Furthermore, the Examiner acknowledged that Caskey does not teach the specifically recited locus combinations. Clearly, the GenBank sequences do not cure the deficiencies of Caskey.

In view of the foregoing, Applicants respectfully request that the rejection of claims 22-25 under 35 U.S.C. 103(a) be withdrawn.

Rejections under the judicially-created doctrine of obviousness-type double patenting

Claim 22 is rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,221,598. Applicants respectfully traversed the rejection of claim 22 in the previous response and filed a terminal disclaimer for U.S. Patent No. 6,221,598, accompanied by the appropriate fee required under 37 C.F.R. 1.321. However, the Examiner indicated that the terminal disclaimer was improper because the instant application number was not indicated in the body of the terminal disclaimer. Applicants submit herewith a terminal disclaimer in which the application number of the instant application is identified in the body of the disclaimer.

Claims 22, 23, and 25 are rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-43 of U.S. Patent No. 5,843,660. In section 7 of the Office Action, which sets forth the basis for this rejection, the Examiner fails to discuss any claim of U.S. Patent No. 5,843,660 as applied to the pending claims, and instead, identified claims of U.S. Patent Nos. 6,221,598 or 5,743,660 that form the basis for rejecting previously canceled claims under the judicially-created doctrine of obviousness-type double patenting. Accordingly, Applicants respectfully traversed the rejection of claims 22, 23, and 25. However, in the interest in advancing prosecution, Applicants submit herewith a terminal disclaimer for U.S. Patent No. 5,843,660 accompanied by the appropriate fee required under 37 C.F.R. 1.321.


The Examiner has rejected claims 22, 23, and 25 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6, 9-18, 21-23, 60-36 (sic), and 39 of U.S. Patent No. 6,479,235. Applicants respectfully traversed the rejection of claims 22, 23, and 25. However, in the interest in advancing prosecution, Applicants submit herewith a terminal disclaimer for U.S. Patent No. 6,479,235 accompanied by the appropriate fee required under 37 C.F.R. 1.321.

This amendment is accompanied by a Request for a Three-Month Extension of Time, three Terminal Disclaimers, and check number 49149 in the amount of \$ 1,510.00 to cover

the fees required under 37 C.F.R. 1.321, 37 C.F.R. 1.17(b), and 37 CFR 1.17(a)(3). No other fee is believed due in connection with this submission. Please charge any additional fee due or credit any overpayment of fees to Deposit Account No. 50-0842.

As the application is now in condition for allowance, Applicants respectfully request withdrawal of the rejections and allowance on the claims.

Respectfully submitted,



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